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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/029,281

Applicant(s)

PARK ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11,13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. 09/693,862.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1, 2, 4-11, 13 and 14 are pending in the present application. This Office action is in response to Paper No. 10, filed 25 March 2003.

#### ***Response to Amendment***

The rejection of claims 1, 2 and 6-11 under 35 U.S.C. 103(a) as being unpatentable over Kresheck et al. (US Patent 5,625,053) in view of Pentecost et al. (Eur. J. Biochem. Vol. 195 No. 3 1991) has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-14 under 35 U.S.C. 103(a) as being unpatentable over Kresheck et al. as applied to claims 1, 2 and 6-11 above, and further in view of Puig et al. (Biochimica et Biophysica Acta Vol. 1397 No. 1 1998) has been withdrawn in view of Applicant's amendment.

The rejection of claims 8-10 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment.

#### ***Rejections Necessitated by Applicant's Amendment***

##### ***Claim Rejections - 35 USC § 103***

Claims 1, 2 4-11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kresheck et al. (US Patent 5,625,053) in view of Pentecost et al. (Eur. J. Biochem. Vol. 195 No. 3 1991) in view of Puig et al. (Biochimica et Biophysica Acta Vol. 1397 No. 1 1998).

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Kresheck et al. teach a method wherein cells are lysed, an alkaline solution is added, and the DNA is precipitated from the resulting solution with a lower alcohol like methanol. Kresheck et al. also teach the limitations of claims 9 and 10 wherein the RNA is lysed with RNase. See columns 2, 4 and 5. Kresheck et al. fails to teach the method using fish spermatogonium. Kresheck et al. also fails to disclose that the cells were disrupted with a rotating-knife crusher or sonicator.

Puig et al. disclose the acetylation of the lysines in histone, H4, which cause the weakening of the attachment of the histone to the DNA. Applicant's method reads on acetylation since the acylation reaction in the claim is mediated by the anhydride compound acetic anhydride.

Pentecost et al. disclose the isolation and extraction of nucleic acids, specifically RNA, from fish spermatogonium. See abstract and page 4873.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize these purification techniques of Kresheck et al. to isolate DNA from various types of eukaryotic cells including fish spermatogonium, as disclosed in Pentecost et al. Kresheck et al. teach a method comprising the same steps claimed by Applicant. Thus, the ordinary skilled artisan would have been motivated to obtain the DNA from the above spermatogonium for a multitude of reasons including sequencing, genetic modification and research, generally. Those of ordinary skill in the art have been isolating DNA from cells for many years such that one would reasonably expect the successful isolation of pollack and squid spermatogonium DNA as well.

It would have been obvious to one of ordinary skill in the art to combine the methods of Kresheck et al., that disclose the isolation of DNA, and the method of Puig et

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al., that disclose the acetylation of histones for the purposes of detaching them from DNA. Although Krescheck et al. does not teach the use of an acetylation reaction to remove proteins bound to DNA. The method steps, specifically the ethanol extraction step, of Kreshek et al. lead to the remove of proteins and protein contaminants in a sample. See column 2. It is germane to the art that DNA isolation methods require the remove of protein contaminants. The differences in these methods relate the extent of deproteination. The histones of Puig et al. like the protamines of the instant claims are proteins attached to DNA, which have a high lysine content. Puig et al. show that the DNA bound proteins, histones, are removed and isolated from the DNA. Although the text of Puig et al. relate to the role of histones the method of separation disclosed on Page 81, shows the complete separation of histones from DNA. Thus, the ordinary skilled artisan would have been motivated to further deproteinate a sample using acetylation reactions such as those disclosed in Puig et al. in a method for genomic DNA isolation. Therefore, without evidence to the contrary, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant has argued that it would not have been obvious to one of skill in the art to use high concentrations of salts in the present methods. Generally, differences in concentration or temperature will not support the patentability of an invention. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Krescheck (see column 4, line 35-60 and column 6, line 30-31), Puig (see page 81) and Pentcost (see page 4873) all teach the use of buffers and solvents comprising salts. Moreover, Applicant admits that processes have previously been disclosed for the isolation of DNA in a large scale with highly concentrated salts. See specification page 1, line 24. Thus, without further

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evidence it would have been obvious to one of skill in the art to optimize the conditions of the present method by routine experimentation.

Applicant has also argued that Kresheck is drawn to the isolation of plasmid DNA, not genomic DNA and is thus inapplicable as prior art. First, the isolation of DNA, plasmid and genomic, is routine in the art. Second, it is not inconsistent to use a reference such as Kresheck, which teaches the isolation of DNA generally, and relate to the isolation of the DNA in the present claims. Puig is provided to cure this deficiency of Kreshek et al. Puig teaches the removal of histones for DNA by acetylation reactions. It would have been obvious to one of skill in the art to remove contaminants such as histones from genomic DNA by acetylation reactions.

Applicant also argues that unexpected results for the present application in the specification, which discloses that the claimed method produces DNAs "without generating pollutants and without resorting to harmful materials such as phenol." This result, however, is not entirely unexpected in view of Kresheck. Kresheck discloses that the method "isolates and purifies DNA from the mixture in the absence of hazardous chemicals such as phenol and chloroform." See column 3, lines 36-38.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
June 2, 2003



JAMES KETTER  
PRIMARY EXAMINER